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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,977	04/16/2004	Eugene H. Gans	01-40326-US-C	8741

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,977	GANS ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on &/25/2008 has been entered.

Claims Rejections 35 U.S.C. 112

a. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 4-10, 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claims recite the employment of penetration enhancer, solvents and emulsifier, and non-solvent/emulsifier, and require particular ratio penetration enhancers/penetration enhancers + solvent and emulsifier. There is no particular amount limitation as to non solvent/emulsifier. However, the application fails to clearly define those terms. Absent clear definition, those terms are not mutually exclusive. For examples, propylene glycol, benzyl alcohol, recited herein as penetration enhancer, are well –known solvent used in pharmaceutical composition. See, e.g., col. 2, lines 49-68 in Konno et al. (US 4, 879,119). Also, isopropyl myristate, recited herein as non-solvent/emulsifier ingredient, is recited by Konno as penetration enhancer. See, col. 3, lines 11-20. The claims are indefinite as to the amounts of the ingredients encompassed thereby.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 4-10 and 13-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,765,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to the claims in '001.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulson (US 3,934,013).

Poulson teaches a topical pharmaceutical composition comprising a propylene glycol, dipropylene glycol, polyethylene glycol with molecular weight of 100-800, or mixture thereof (col. 6, lines 20-38) and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, in cream composition see col. 11, lines 44-60, see also col. 10, CREAM BASE, and 94.8-99% in lotion. Poulson also teaches the amount of surfactant is in the composition is about 0.1 to 5 %, and preferred range is 0.5 to 2% in lotion (col. 14, line 30-56). Fatty alcohol is in the range of 1-20%, preferred 5-10% in cream (col. 10, line35-42) and the amount of fatty ester in lotion is about 0.10 to 10%, preferred 0.5-2% (col. 14, lines 50-55).

Poulsen (USPN 3,934,013) does not teach some of the particular percentages of corticosteroid or propylene glycol herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ corticosteroid; and mixture of propylene glycol, dipropylene glycol, and/or polyethylene glycol; and a surfactant in the particular weight percentages claimed herein.

One of ordinary skill in the art would have been motivated to employ corticosteroid; and mixture of propylene glycol, dipropylene glycol, and/or polyethylene glycol; and a surfactant in

the particular weight percentages claimed herein, because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

Note the ratio claimed herein would be met if the composition comprising 95% or more, and 0.1% of surfactant.

4. Claims 1, 2, 4-7, 10 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulson (US 3,94234,013), in view of Bennett (IDS).

Poulson teaches a topical pharmaceutical composition comprising a propylene glycol and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, in cream composition see col. 11, lines 44-60, see also col. 10, CREAM BASE, and 94.8-99% in lotion. Poulson also teaches the amount of surfactant in the composition is about 0.1 to 5 %, and preferred range is 0.5 to 2% in lotion (col. 14, line 30-56). Fatty alcohol is in the range of 1-20%, preferred 5-10% in cream (col. 10, line35-42) and the amount of fatty ester in lotion is about 0.10 to 10%, preferred 0.5-2% (col. 14, lines 50-55).

Poulsen (USPN 3,934,013) does not teach expressly the employment of second enhancer, or some of the particular percentages of corticosteroid or propylene glycol herein.

However, Bennett et al. teaches that combine two or more penetration enhancer, such as propylene glycol with azone and DMF is better than propylene glycol alone. See, particularly, the abstract.

Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ two or more penetration enhancers as taught by Bennett in the composition of Poulsen.

One of ordinary skill in the art would have been motivated to employ two or more penetration enhancers as taught by Bennett in the composition of Poulsen because such combination are known to provide better efficacy of the active agent.

Further, the employment of corticosteroid and propylene glycol in the particular weight percentages claimed herein would have been within the purview of ordinary skilled artisan because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

5. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (US 3,934,013) as applied to claims 1-7 and 10, 13-19 above, and further in view of PDR entries of Lidex-Synalar.

Poulsen (USPN 3,934,013) does not teach the employment of the second penetration enhancer recited in the claims.

PDR entries of Lidex-Synalar teaches the employment of propylene glycol and diisopropyl adipate together in a topical fluocinonide composition. PDR also teaches different excipients and adjuvants that can be employed in a topical fluocinonide composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the two penetration enhancers and any known pharmaceutical necessity in the amounts herein in a corticosteroid topical composition, such as fluocinolone composition.

One of ordinary skill in the art would have been motivated to employ the two penetration enhancers and any known pharmaceutical necessity in the amounts herein in a corticosteroid composition, such as fluocinonide composition, because the two are known to be used together in such composition. Further, optimization of amounts of the penetration enhancers the optimization of a result effective parameter, e.g., amounts of the penetration enhancers, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Note penetration enhancers in topical pharmaceutical composition have been recognized as result affecting factor.

Response to the Arguments

Applicants' amendments and remarks submitted July 25, 2008 have been fully considered, but are not persuasive.

Applicants' contend that the examiner misunderstood the claims. The examiner respectfully disagrees. As it is well settled that during examination, claims are given its broadest interpretation. The claims are drawn to a composition comprising corticosteroids and a variety of well-known pharmaceutical excipients in particular amounts that are within the range disclosed by the prior art. The merely arbitrary definitions of the excipients would not make a composition comprising them patentably distinct.

6. In response to applicant's argument that the cited references do not teach or particularly suggest the ratio of p/p+s+e, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227

USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The recited ratio would have been met if one of ordinary skill in the art follows the teaching and suggestions from the cited references.

7. As discussed above, the terms penetration enhancer, solvent/emulsifier, non-solvent/emulsifier, note the application lack a mutual exclusive definitions and therefore may be interpretated broadly. Note the specification states that any fatty solvent may function as penetration enhancers.

Applicants' remarks regarding unexpected results are untenable. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.132 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e). Particularly, the evidence on the record merely shows two particular combinations exhibiting unexpected benefit. There is no evidences, rationale that such benefit would be extrapolated to the scope as herein claimed. Furthermore, the terms penetration enhancer, solvent/emulsifier, and non-solvent/emulsifier are arbitrary defined and not mutually exclusive. As pharmaceutical art is unpredictable, the claims herein reach a territory that is unpredictable and undefined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617